IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gorringe *et al.*

Appl. No. 09/763,750

§ 371 date: June 4, 2001

For: **Superoxide Dismutase as a Vaccine Antigen**

Confirmation No. 1196

Art Unit: 1645

Examiner: Ford, V.L.

Atty. Docket: 1581.0780000/RWE

Petition to Reset Period for Reply

Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants hereby request that the period for replying to the outstanding Restriction Requirement be reset. Instead of running from the stated mailing date of December 4, 2001, Applicants request that the period for reply be reset to run from **January 29, 2002** which is the date of receipt of the Restriction Requirement at the correspondence address.

Applicants believe that the Restriction Requirement was received late due to delays in the U.S. Postal Service. As evidence that delays in the U.S. Postal Service are responsible for the late receipt of the Restriction Requirement, Applicants submit herewith a photocopy of the Restriction Requirement, indicating that it arrived at the correspondence address 56 days after it was sent.

Applicants submit that the period for reply should be reset because the following criteria, as set forth in MPEP § 710.06, have been met:

(A) This petition is being filed within two (2) weeks of the date of receipt of the Restriction Requirement;

(B) A substantial portion of the set reply period had elapsed on the date of receipt of the Restriction Requirement; *i.e.*, more than the entire one (1) month reply period had elapsed as of January 29, 2002; and

(C) (1) As evidence showing the date of receipt of the Restriction Requirement at the correspondence address, Applicants submit herewith a photocopy of the Restriction Requirement having the date of receipt of the stamped thereon; and

(2) Applicants state that the date of receipt of the Restriction Requirement at the correspondence address is **January 29, 2002**. The enclosed photocopy of the Restriction Requirement establishes the date of receipt of the Restriction Requirement at the correspondence address by the date stamp indicating "JAN 29 2002." The date stamp was mechanically placed on the Restriction Requirement at the time it was received at the correspondence address.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond

Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

Date: Feb 7, 2002

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,750	06/04/2001	Andrew Richard Gorringe	1581.0780000	1196

7590 12/04/2001

Sterne Kessler Goldstein & Fox
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Washington, DC 20005-3934

EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	9

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

AMD 1/29
RWE 1/29 RWE

Restriction/Election Due January 4, 2002

STAT BAR JUNE 4, 2002

Applicant's Copy

Office Action Summary	Application No.	Applicant(s)	
	09/763,750	GORRINGE ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 28-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-20 and 28-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Election/Restrictions

Group I	Claims 1-5, 6-8, 10-13 and 15-17 are drawn to a pharmaceutical composition and vaccine comprising a bacterial Cu,Zu-superoxide dismutase or fragments, derivatives or variants thereof.
Group II	Claims 1-5 and 6-8 are drawn to a pharmaceutical composition and vaccine comprising a nucleic acid that encodes a bacterial Cu,Zu-superoxide dismutase or fragments, derivatives or variants thereof.
Group III	Claim 9 is drawn to a method of preparing a pharmaceutical composition comprising isolating a gene for a bacterial Cu,Zu-superoxide dismutase or fragments, derivatives or variants thereof.
Group IV	Claims 10 and 13-14 are drawn to a pharmaceutical composition comprising an antibody to a bacterial Cu,Zu-superoxide dismutase or fragments, derivatives or variants thereof.

Group V Claims 18-20 and 31-33 are drawn to a method of treating an individual with a bacterial infection comprising administering bacterial Cu,Zu-superoxide dismutase or fragments, derivatives or variants thereof.

Group VI Claims 28-29 and 34 are drawn to a method of treating an individual with a bacterial infection comprising administering an antibody specific to a bacterial Cu,Zu-superoxide.

Group VII Claim 30 is drawn to a method of treating an individual with a bacterial infection comprising administering a nucleic acid encoding a bacterial Cu,Zu-superoxide.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
Group I lacks novelty under PCT Article 33(2) as being anticipated by Nippon *(JP 04327541A, published November 1992)* discloses a pharmaceutical composition comprising bacterial Cu,Zu-superoxide dismutase (see the entire Abstract). Group I is the main invention in this application and it lacks novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

3. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
November 29, 2001

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice of References Cited	Application/Control No. 09/763,750	Applicant(s)/Patent Under Reexamination GORRINGE ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification	
	A	US- -				
	B	US- -				
	C	US- -				
	D	US- -				
	E	US- -				
	F	US- -				
	G	US- -				
	H	US- -				
	I	US- -				
	J	US- -				
	K	US- -				
	L	US- -				
	M	US- -				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification	
	N	-JP 04 327541-A	11-1992		Nippon Kayaku KK		
	O	- -					
	P	- -					
	Q	- -					
	R	- -					
	S	- -					
	T	- -					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

XP-002128008

AN - 1992-430060 [42]
AP - JP19910117929 19910423
CPY - NIPK
DC - B04 D16
FS - CPI
IC - A61K37/50
MC - B04-B02C2 B12-D02B D05-A02A
M1 - [01] M423 M720 M781 M903 N135 P433 Q233 V802 V811; 9240-7
PA - (NIPK) NIPPON KAYAKU KK
PN - JP4327541 A 19921117 DW199252 A61K37/50 004pp
PR - JP19910117929 19910423
XA - C1992-191133
XIC - A61K-037/50
AB - J04327541 Therapeutic drug contains active substance of human Cu-Zn superoxide dismutase obtd. by gene-recombination.
- The organ is heart, liver, lung, kidney or skin. The therapeutic drug contains 1,000 unit/kg - 2,000,000 unit/kg of Cu-Zn superoxide dismutase (r-hSOD). The drug can contain additive (e.g., lactose or sugar).
- USE/ADVANTAGE - Used as a pharmaceutical of organ transportation.
- In an example, SOD (700,000 unit), sodium phosphate (5m mols), and edible salt (10mg) are formed into SOD freeze-dried powder, which was dissolved in refined water (10ml) with white sugar (20mg), then freeze-dried in a vial (5ml). (Dwg.0/5)
DRL - 9240-7
IW - THERAPEUTIC DRUG IMMUNO REACT ORGAN AFTER TRANSPLANT CONTAIN ACTIVE SUBSTANCE HUMAN COPPER ZINC SUPER OXIDE DISMUTASE OBTAIN GENE RECOMBINATION
IKW - THERAPEUTIC DRUG IMMUNO REACT ORGAN AFTER TRANSPLANT CONTAIN ACTIVE SUBSTANCE HUMAN COPPER ZINC SUPER OXIDE DISMUTASE OBTAIN GENE RECOMBINATION
NC - 001
OPD - 1991-04-23
ORD - 1992-11-17
PAW - (NIPK) NIPPON KAYAKU KK
TI - Therapeutic drug for immuno-reaction organ after transplantation - contg. active substance of human copper-zinc super:oxide dismutase obtd. by gene recombination

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.